

## REMARKS

### *Claim Amendments*

The Applicants have read the Examiner's Office Action of April 20, 2004 and have the following comments. Applicants emphatically do not agree that the claims concerning which the Examiner alleged lack of written description or enablement were unpatentable in that form. However, in order to expedite prompt allowance of the Applicants' preferred embodiment of the invention Applicants have, without prejudice to presenting the original claims in a continuation or divisional application, amended the broadest claims to indicate that the neuroprotective compound is an alpha 2 receptor agonist. Basis for this amendment is found in the claims as filed.

### *Request for Withdrawal of Finality of the April 20, 2004 Office Action*

The Examiner's most recent Office Action continues to reject claims 13-17, 19-20 and 24-25 under 35 USWC §112 first paragraph as in the previous Office Action. However, the previous Office Action alleged that the claims lacked sufficient written description. By contrast, the response to Applicant's remarks now appears based on a new ground of rejection; that of enablement. Thus, it is stated "the specification does not provide guidance to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims", and "one of skill in the art would be burdened with undue experimentation to determine all compounds which would be able to protect the ocular neural tissue against damage and injury." April 20, 2004 Office Action, pages 2 and 3.

MPEP 706.07(a) states a "second or any subsequent action on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information filed during the period set forth in 37 CFR 1.97(c) . . ."

As Applicants did not amend the claims, and the current rejection is not a prior art rejection, Applicants respectfully request the Examiner to withdraw the finality of this Office Action.

### *Written Description Requirement*

The pending claims (13-25) were rejected as allegedly in violation of the written description requirement of 35 USC 112. Applicants traversed this rejection in the Reply of December 19, 2003, the remarks of which are hereby incorporated by reference herein.

The April 20, 2004 Office Action does not specifically address any of the arguments made by Applicants in rebutting the written description rejection. Instead, it raises new issues against the same pending claims based on enablement. As stated in the last reply, the Examiner has not produced sufficient

evidence or technical reasoning addressed to this rejection to overcome the “strong presumption” that an adequate written description has been provided. See *PTO Final Examiner Guidelines on Written Description Requirement*, 66 FED. REG. 1099 (BNA Patent, Trademark and Copyright J., January 12, 2001 at comment 3.

Moreover, it is clear that the claims as amended are thoroughly described in the specification. Page 4 of the specification describes the alpha adrenergic receptors and the difference between the alpha and beta receptors. Page 9. The specification gives specific examples of brimonidine, clonidine, and the compounds AGN 960, 795, and 923, as well as many other compounds incorporated by reference as part of the specification in US Patents 6,313,172 and publications WO0178703, WO0178702 and WO9928300. See page 16, lines 26-28.

For these reasons the Applicants respectfully request the Examiner to withdraw this ground of rejection.

#### *Enablement*

As mentioned above, the Examiner has stated that “the specification does not provide guidance to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims”, and “one of skill in the art would be burdened with undue experimentation to determine all compounds which would be able to protect the ocular neural tissue against damage and injury”. These arguments, although not formally so attributed, are based on the enablement requirement of 35 USC §112 first paragraph; Applicants respectfully traverse this rejection on that basis for the following reasons.

The present claims, as amended, claim the use of an alpha 2 receptor agonist as an adjunct to techniques such as photodynamic therapy and photocoagulation as a means of preventing the significant degree of neural damage and vision loss that normally accompanies these procedures.

Alpha 2 receptor agonists such as clonidine, apraclonidine, dexmedetomidine and brimonidine have been known and used for many years; clonidine has been used since the 1960s. Additionally, the patent and publications incorporated by reference as part of the present specification disclose many more alpha 2 receptor agonists, including diverse compound classes such as thioureas and imidazoles and their method of synthesis therein.

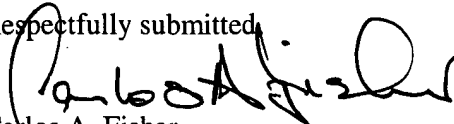
Moreover, US Patent 6,313,172, incorporated by reference as part of the present specification, describes in Example Y methods for measuring alpha.2 agonist selectivity in the RSAT (Receptor Selection and Amplification Technology) assay reported in Messier et al. (1995) "High throughput assays of cloned adrenergic, muscarinic, neurokinin and neurotrophin receptors in living mammalian cells", *Pharmacol. Toxicol.* 76:308-11. Thus, the present application also describes high throughput methods of screening

compound libraries, for example, commercially available compound libraries, to easily discover alpha 2 adrenergic agonists.

For these reasons the Applicants respectfully assert that sufficient disclosure of alpha 2 agonists have been disclosed in the specification and would be available to the skilled artisan in light of the well-known art. Thus, Applicants ask the Examiner to withdraw the rejection and permit the claims to proceed to issue.

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Respectfully submitted,



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